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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

**Issuance and Enforcement Guidance for Dog Confinement
Agreements**

Agency: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice of Agency Guidance.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is publishing this issuance and enforcement guidance for dog confinement agreements under 42 CFR 71.51. Under 42 CFR 71.51(c)(2), the CDC Director may authorize admission into the United States of a dog that has not been vaccinated for rabies or that is inadequately immunized if the owner agrees to subsequently vaccinate and properly confine the dog. This guidance describes the factors that HHS/CDC will consider in determining whether it will issue a dog confinement agreement allowing entry of a dog that has not been adequately immunized against rabies, or whether the dog(s) will be denied entry.

The notice also describes the steps that an importer may take if his/her imported dog is denied entry.

DATES: This guidance is effective on [INSERT 30 DAYS AFTER DATE OF PUBLICATION]

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION

I. Background

Rabies is caused by a virus that is fatal in humans and animals. In September 2007, at the Inaugural World Rabies Day Symposium, HHS/CDC declared the United States to be free of the canine variant of the rabies virus. However, this rabies virus variant remains a serious public health threat in many other countries where laboratory and epidemiologic surveillance for canine variant rabies virus is not as strong as in the United States. Many other countries also do not maintain a robust rabies vaccination program for dogs. Preventing the entry of animals infected with the canine

variant of rabies into the United States is a public health priority. Globally, canine variant rabies viruses are responsible for 98% of the estimated 55,000 human rabies deaths worldwide each year (WHO, 2004 [Page 116]).

II. Authority and Operations

Under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), the Secretary of Health and Human Services, has the authority to make and enforce such regulations as in his or her judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Secretary may authorize a variety of public health measures, including inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures.

Regulations that implement Federal public health authority with respect to the importation of certain animals are currently published in 42 CFR part 71. The Secretary has delegated to the Director of the CDC the authority for implementing these regulations. Authority for carrying out

most of these functions has been delegated to HHS/CDC's Division of Global Migration and Quarantine (DGMQ). To carry out its mission of protecting public health, CDC/DGMQ implements its regulations through already established and extensive partnerships with local, national, and international health authorities. DGMQ maintains quarantine stations at major U.S. ports of entry that fulfill a primary purpose in reducing the risk of introduction of communicable diseases into the United States.

Since 1956, Federal quarantine regulations have controlled the entry of dogs into the United States. See 21 FR 9870, Dec. 12, 1956. Currently, HHS/CDC regulates imports of dogs into the United States under regulations found at 42 CFR 71.51. Among the principal concerns for regulating the import of dogs is to prevent introduction and spread of rabies.

Upon arrival to the United States, dogs are subject to inspection and may be denied entry if they show signs of infection with a communicable disease or if they have not been adequately immunized against rabies. If a dog appears to be ill, further examination by a licensed veterinarian, at the owner's expense, may be required before the dog is admitted into the United States. Currently, licensed rabies vaccines have not been shown to be effective when administered to dogs

aged less than 3 months. Additionally, full immune response to the vaccine in dogs that have never been previously vaccinated does not occur until approximately 30 days after vaccination. Therefore, under HHS/CDC's current regulations, puppies may not be vaccinated against rabies earlier than 3 months of age and previously unvaccinated dogs are only considered adequately immunized 30 days post-vaccination. Adult dogs that have previously been adequately immunized against rabies, but whose rabies vaccination certificates have expired, are considered adequately immunized immediately following administration of a booster vaccination.

III. Confinement Agreements

Under § 71.51, HHS/CDC currently requires each imported dog to be accompanied by a valid rabies vaccination certificate indicating that the animal has been vaccinated against rabies prior to entry into the United States. The exceptions to this requirement are for dogs from rabies-free countries and dogs imported for scientific research purposes when rabies vaccination would interfere with the purpose of the research. This provision defines a valid rabies vaccination certificate as a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.

However, subsection 71.51(c)(2) indicates that "the [CDC] Director may authorize admission" of dogs that have not been adequately immunized against rabies provided that the dogs are confined under conditions that restrict their contact with humans and other animals until they have been immunized. Generally, the use of the term "shall" in a regulation indicates a regulatory requirement, while the use of the term "may" indicates that the agency has discretion regarding the manner in which it chooses to enforce this particular aspect of its regulations. Through this notice, and as discussed in more detail below, HHS/CDC is informing the public of the manner in which it applies its discretion in the issuance and enforcement of confinement agreements.

HHS/CDC reviews rabies vaccination certificates to determine whether they may be expired, invalid or suspect e.g. dog appears younger than is stated or does not match the breed, sex, color, or markings described) in its assessment of whether a dog is "adequately immunized." Following physical inspection of the dog and documentation, if HHS/CDC determines that a dog has not been adequately immunized, HHS/CDC may enter into a confinement agreement with the importer.

Section 71.51 defines Confinement as the "restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog is allowed out of the enclosure, muzzling and keeping it on a leash." HHS/CDC Form 75.37 "Notice to Owners and Importers of Dogs" explains the confinement requirements and serves as a binding "confinement agreement" with the importer. This form is approved under OMB# 0920-0134 Foreign Quarantine Regulations (expiration 07/31/15). Under 42 CFR 71.51(c)(3), HHS/CDC shares the confinement agreement with the state agency "having jurisdiction at the point of destination ... to facilitate surveillance and other appropriate action." Confinement agreements are intended to ensure that travelers seeking to enter the United States with their personal pet dogs have an alternative to their dogs being

denied entry to the United States if they were not adequately immunized against rabies.

The intent of the confinement agreements between HHS/CDC and the importer is to ensure that inadequately immunized dogs will be confined in such a way as to minimize the risk of exposing persons and other animals especially dogs to rabies until the dogs are considered adequately immunized against rabies. HHS/CDC considers confinement agreements to constitute an exception to the general rule that, unless coming from a rabies-free country or intended for use in scientific research where rabies vaccination would interfere with that research, all imported dogs must be properly vaccinated against rabies. HHS/CDC issued two dog confinement agreements to individuals in 2006 and 10 agreements in 2007. This number has continued to multiply and as of June 27, 2014, 853 confinement agreements have been issued in 2014 (See Table 1 below).

Table 1

Year	Dog Confinement Agreements Issued by HHS/CDC
2006	2
2007	10
2008	41
2009	179
2010	412
2011	1814
2012	2131
2013	1733
2014*	853
Total	7175

*As of June 27, 2014

HHS/CDC along with state and local agencies with jurisdiction has discovered that, in some circumstances, the terms of confinement agreements are not carried out by the importer. State and local public health agencies who have jurisdiction to enforce confinement agreements have reported to HHS/CDC that some importers have either knowingly or unknowingly provided inaccurate information on the agreement regarding confinement location. In other circumstances, upon follow up on the confinement of the dogs, state and local authorities have reported that the dogs were not properly confined per the terms of the confinement agreement (i.e., the dog was not kept in isolation from other animals and from persons except for contact necessary for its care or, if the dog was allowed out of the enclosure, was not muzzled and kept on a leash).

With the substantial increase in recent years in the number of confinement agreements being requested by importers of dogs, supervision of confinement agreements to identify and address violations as described above has become administratively burdensome. The investigations conducted have revealed that in many cases where importers have violated their confinement agreements, these confinement agreements were issued to persons who import dogs for commercial purposes

or for reasons other than as personal pets, which is contrary to the intent of the confinement agreement provisions.

When state and local public health authorities follow up on the confinement agreement notifications and determine that the importer is in violation of the agreement, these authorities inform HHS/CDC. In 2009, HHS/CDC began issuing warning letters to known violators of dog confinement agreements. Warning letters inform importers that they have violated the legally binding confinement agreement, remind them of their obligations under federal law, and warn them that further violations might result in referral of the matter to the United States Attorney for criminal prosecution. During fiscal year 2013, over 20 dog importers, including those who import more than 1-2 shipments of dogs per year into the United States, received warning letters from HHS/CDC for failure to comply with the confinement agreement.

IV. Provisions of this Notice

Because of the risk that inadequately immunized dogs pose to public health, HHS/CDC is issuing this guidance describing how it will use its discretion in issuing confinement agreements to dog importers. In determining whether a confinement agreement will be issued, HHS/CDC will take several factors into account to ensure that the terms of the

confinement agreement will not be violated or that an inadequately immunized dog does not pose a threat to public health. Non-issuance of a confinement agreement will usually result in denial of entry of the dog(s). "Denial of entry" usually entails the immediate return of the dog(s) to the country of origin at the importer's expense. The care of the dog(s) until their final disposition is also at the importer's expense.

Among other important factors which may pose a risk to public health, below are circumstances that HHS/CDC will consider in determining whether it will issue a dog confinement agreement:

(1) The number of dogs presented for import must be consistent with the purposes of the dog confinement agreement;

(2) The frequency of dog imports must be consistent with the purposes of the dog confinement agreement;

(3) History of non-compliance with HHS/CDC-issued confinement agreements;

(4) Prevalence of rabies in country of origin (country where the dog has lived during the 6 months prior to arrival, or since birth if the dog is less than 6 months of age); and

(5) Other risk factors as determined by the CDC Director. HHS/CDC will evaluate each import based on the totality of the circumstances.

If an importer is denied the opportunity to receive a confinement agreement, the denial will be issued in writing. The letter of denial received will include reasons for denial as well as detailed instructions on whom to contact for questions, including name, address, and telephone number, as well as how to submit an appeal. Persons who wish to contest HHS/CDC's determination will have five business days after receiving the letter of denial. The importer must submit the appeal in writing to the CDC Director, stating the reasons for the appeal and showing that there is a genuine and substantial issue of fact in dispute. HHS/CDC will issue a written response, which shall constitute final agency action. The appeal will be reviewed and decided upon by an HHS/CDC senior management official who will be senior to the employee who issued the initial letter of denial.

Since animals denied entry to the United States will be re-exported immediately under standard operating procedures at U.S. ports of entry, any successful appeal of a denial of entry after the dog(s) has already been re-exported would only permit the importer to reimport the dog(s) into the United States under the requirements of the confinement agreement. The appeal would not entitle the importer to recover any costs related to the re-export and reimport of the dog(s). The

policy and program operations described above will become effective on [INSERT 30 DAYS AFTER DATE OF PUBLICATION].

Dated: July 7, 2014.

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